

RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claim 1 is amended to recite the limitations of claim 8, and claim 8 is cancelled without prejudice. No new matter is added. Claims 1-7 and 9-16 are now pending and are presented herein for reconsideration.

B. Rejection under 35 U.S.C. § 103

The Action rejects claims 1-16 under 35 U.S.C. § 103(a) as being obvious over Zhong *et al.* (*Planta* 187: 483-489, 1992; “Zhong”), in view of Bowen *et al.* (U.S. Patent 5,736,369; “Bowen”), Cheng *et al.* (*Plant Physiol.* 115: 971-980, 1997; “Cheng”); Bartók *et al.*, (*Pl. Cell Tiss. Org. Cult.* 22:37-41, 1990; “Bartók), and Weeks *et al.* (*Plant Physiol.* 102: 1077-1084, 1993; “Weeks”). Applicants traverse in part, while noting that claim 1 has been amended.

1. The Mesocotyl Explant of Bartók is Distinct From That of the Present Invention

Applicants note that the corn explant used by Zhong explicitly contains “...a shoot tip, three to five leaf primordia, and a portion of young leaf and stem immediately below the leaf primordia...” (Zhong, p.483, right column, 1st paragraph of “Materials and Methods”). Applicants also draw the Examiner’s attention to Fig. 19-7 in Exhibit 1 of the Appeal Brief filed in the present case on February 19, 2008, which consists of pp. 383-385 from Salisbury & Ross, Eds., *Plant Physiology*, 3rd Ed., Wadsworth Publ., 1988). This figure illustrates a maize seedling, showing the location of the mesocotyl with respect to other structures. In view of Zhong’s description and Fig. 19-7, it is clear that his explant does not comprise a node, let alone a mesocotyl, which is an internode (stem) structure and is located below the node. This

defect in Zhong is implicitly conceded in the Action, in that the Bartók reference is also asserted regarding claim 8 (and presumably claim 13), by teaching use of a “wheat mesocotyl”.

However, Applicants further note that Bartók, at p. 38, left column, and in their abstract, for instance describes their “mesocotyl explant” as being prepared by having “...most of the germ tissues [*i.e.* germ being typically defined as both the embryo and scutellum fractions of the wheat kernel] removed by means of four cuts with a scalpel, so that **only mesocotyl** [*i.e.* internode] **remained on the scutellum**” [emphasis added]. Thus Bartók apparently contemplates cuts which leave the mesocotyl attached to the scutellum, but essentially remove most of the rest of the germ (embryo), resulting in the removal, among other tissues, of the coleoptile, shoot apex, radicle, and associated nodes and meristems. Thus, the “prepared embryo” explant of Bartók apparently lacks multiple meristems described in the present Specification at ¶¶30-31 and in present Fig. 1, presumably including the shoot apical meristem, the coleoptile with leaf and bud primordia, and nodes associated with these structures. Rather, Bartók utilizes plant cell tissue culture to obtain organogenic callus and *de novo* formation of meristematic tissue (*e.g.* see Bartók, Fig. 2). In contrast, the presently defined single mesocotyl explant includes germ tissue, *i.e.* mature or immature embryonic tissue, and the associated plurality of meristems. Bartók’s “mesocotyl explant” is thus **not equivalent** to the mesocotyl explant presently described, in spite of the terminology being used. In view of this, the addition of Bartók does not cure the defect in Zhong relating to use of wheat mesocotyl tissue. “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir.

1988). M.P.E.P. 2143.03. Thus, Applicants submit that no properly reasoned *prima facie* case for the obviousness of claims 1-16 has been made, and withdrawal of the rejection is respectfully requested.

2. Combining Bartók with Zhong Changes the Principle of Operation of Zhong

Zhong describes organogenesis of shoot tip explants “without apparent callus formation” (*e.g.* see Zhong, p. 486, left column). In contrast, the prepared explants of Bartók lack shoot tips (*e.g.* compare Bartók Fig. 1B with Fig. 1A), and they are specifically utilized in conjunction with induction of callus. Indeed, the experimental approaches described in these two references are not only distinct as to these two criteria, but further for instance as to whether plant growth media comprising cytokinin or auxin are to be utilized (*e.g.* compare Zhong medium B, containing the cytokinin benzyladenine but no added auxin, vs. the initial growth medium of Bartók, containing the auxin 2,4-D, but no cytokinin). Therefore, combining Bartók with Zhong, would clearly change the principle of operation of Zhong *et al.* if the explants of Bartók were utilized with the tissue culture conditions of Zhong, as apparently asserted, let alone if other aspects of Bartók’s teachings were utilized with Zhong.

“If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)...The court reversed the rejection holding the “suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.” 270 F.2d at 813, 123 USPQ at 352.). [M.P.E.P. 2143.01 VI]

Thus these references are not properly combined, and cannot establish a *prima facie* case for obviousness. Withdrawal of the obviousness rejection, in view of the above, is therefore respectfully requested.

3. A Skilled Worker Would Have Had No Expectation of Success in Combining Zhong and Bartók.

The distinct tissue culture approaches described by the Zhong and Bartók references would not motivate a skilled worker to combine them, nor would they lead a skilled worker to any expectation of success if or when various aspects of the distinct and often contradictory teachings were to be combined. Applicants submit for instance, that it is unclear even how the teachings of these references might be combined, since the growth conditions of the Zhong reference are designed to effect direct **organogenesis** (*e.g.* multiple corn shoot clumps) by growth in the presence of benzyladenine (a cytokinin; see p. 484, left column), while on the other hand Bartók describes conditions for **callus induction** of wheat explants and subsequent shoot formation (*i.e.* apparently indirect organogenesis), initially utilizing only an auxin (2,4-D; see p. 38, left column) without cytokinin, and then transferring developing calli to hormone-free medium. It is entirely unclear which tissue culture parameters, among the many available in these two references, should be utilized if the teachings of these references were to be successfully combined.

For instance, Applicants submit that a skilled worker simply would not have known whether growth of the wheat “mesocotyl explant” described by Bartok, as opposed to shoot tips (described by Zhong), in the presence of benzyladenine (a cytokinin; the initial plant hormone regime taught by Zhong, see Fig. 1, medium “B”) would result for instance in organogenic calli (*e.g.* Bartok, p. 40, right column), multiple shoot cultures (*i.e.* direct organogenesis; *e.g.* see

Zhong, Fig. 1, medium B), or direct adventitious shoot formation (*e.g.* Zhong Fig. 1, medium C), also probably depending on the amount and ratio of auxin and/or cytokinin in various media subsequently being used. The rejection, in picking and choosing various individually asserted portions of the teachings of the two references, thus displays improper hindsight in concluding that a skilled worker would make such choices, and provides no reasoning to support the assertion that a skilled worker would have had an expectation of success in doing so, or even any reasoning to support an assertion that Bartók's explants could be grown with Zhong's tissue culture medium B to yield multiple shoot cultures, especially since Zhong's medium B contains cytokinin without auxin, while Bartók's initial culture medium contains auxin without cytokinin, and even Bartók's later culture medium has no added cytokinin. Since the described hormonal conditions and explant materials are distinct, the effects of the plant hormone regime of Zhong on the explant of Bartók would be unclear and unpredictable. Thus, there would have been no reasonable expectation of success in combining these references. M.P.E.P. 2143.02. Withdrawal of the rejection is therefore respectfully requested.

4. The Method of the Present Invention Provides Unexpected Results

Applicants also note that Zhong Fig. 1 describes the steps for obtaining multiple shoot cultures as being 4 weeks long, while other steps require at least an additional 6-19 weeks (Zhong, Fig. 1). This is apparently because the shoot tip explants of Zhong contain the shoot tip, some leaf primordia, and some stem. However, they lack nodal tissue, and thus also lack other meristems found at such nodal structures (see Specification, ¶ 0030). Indeed, Zhong specifically teaches that such structures are removed from their explants, and then proceeds to spend multiple weeks in tissue culture, for instance using media B or C as summarized in their Fig. 1, to apparently recreate tissues containing multiple meristems or multiple shoots (*e.g.*

their multiple shoot clumps or their directly formed adventitious shoots). The present invention, which takes advantage of multiple meristems pre-existing in a single explant, including apical meristem and axillary meristems from shoots, buds, and leaves, allows a skilled worker, in contrast, to rapidly and efficiently multiply the amount of tissues useful for transforming cells and regenerating transformed plants. Thus, by 3-5 weeks, multiple bud clumps arising from pre-existing meristem could be transferred to a shoot elongation medium (Present Specification, for instance at ¶¶0062- 0064) for rooting, without a need for *de novo* meristem formation, or callus formation (¶0065), allowing the presently described invention to rapidly and efficiently yield rooted shoots. Finally, the teachings of Zhong and Bartok relating to explant preparation, in which numerous **meristems are removed from their explants**, directly **teach away** from the methods of the present invention, which utilizes the tissue culture responses of pre-existing multiple meristems (*e.g.* see ¶0067) to allow for direct organogenesis and rapid multiplication of useful tissues.

The other cited references (Bowen, Cheng, and Weeks) do not cure the defects discussed above, relating to use of mesocotyl explants, and are not asserted to do so. In view of the amendment of claim 1, Applicants submit that (1) the “mesocotyl” explant of Bartok is distinct from the presently utilized explant; (2) Zhong *et al.* is not properly combinable with Bartók; (3) any such combination would not lead to an expectation of success; and (4) the present results are unexpected and the cited Zhong and Bartok references teach away from them. Thus, no proper *prima facie* case for obviousness has been presented. Withdrawal of the rejection is therefore respectfully requested.

C. Rejection for double patenting

The Action next rejects claim 1 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 5,631,152 (Fry *et al.*). Applicants respectfully traverse.

Applicants submit that the asserted double patenting rejection is improperly utilizing the Fry reference as prior art when it asserts that “...the steps [of Fry] are similar to those of the instant application [Action, p. 8]. “When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent **may not be used as prior art**. *General Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992)” [M.P.E.P. 804 II. B. 1; emphasis added] Further, Applicants bring to the Examiner’s attention the decision made in U.S. Patent Application 10/162,464, Appeal 2007-1626 (attached as **Exhibit 1**). At pp. 2-4 of the decision, the Board found that the proper issue in a double patenting rejection is whether the present claims define something which is an obvious variant of what is claimed in the cited reference. Applicants respectfully submit that in contrast to present claim 1, Fry claim 1 contains no teaching relating to the use of mesocotyl tissue as is presently claimed, or relating to induction of a plurality of buds from a single explant. Additionally, Fry claim 7 relates explicitly to production of embryogenic wheat callus, which is not recited in the present claims, let alone in the present invention as described in the Specification. Nor does Fry claim 7 recite or suggest use of mesocotyl tissue. Since the present claims do not represent an obvious variant of the invention defined in claims 1 and 7 of the Fry reference, withdrawal of the double patenting rejection in view of Fry is respectfully requested.

D. Conclusion

In view of the above, it is submitted that all of the rejections to the claims have been overcome, and the case is in condition for allowance.

The Examiner is invited to contact the undersigned at (214) 259-0932 with any questions, comments, or suggestions relating to the references patent application.

Respectfully submitted,

/Ron J. Laby/

Ron J. Laby
Reg. No. 53,173
Agent for Applicants

SONNENSCHN NATH &
ROSENTHAL L.L.P.
2000 McKinney Ave., Suite 1900
Dallas, Texas 75201
(214) 259-0931

Date: November 3, 2009

EXHIBIT 1

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte WILLIAM P. DONOVAN
JUDITH C. DONOVAN and ANNETTE C. SLANEY

Appeal 2007-1626
Application 10/162,464
Technology Center 1600

Decided: January 28, 2008

Before TONI R. SCHEINER, ERIC GRIMES, and NANCY J. LINCK,
Administrative Patent Judges.

GRIMES, *Administrative Patent Judge.*

DECISION ON REQUEST FOR REHEARING

Appellants have requested rehearing of the decision entered September 12, 2007 (hereafter “Decision”), which affirmed the rejection of claims 55-58 and 69 for obviousness-type double patenting. We agree with Appellants that the Decision reflects a misinterpretation of the law of obviousness-type double patenting. The request for rehearing is granted.

DISCUSSION

Many of the arguments made in Appellants' Request for Rehearing are new arguments that were not raised in the Appeal Brief. We have not considered the new arguments raised for the first time in the Request for Rehearing. *See* 37 C.F.R. § 41.52(a)(1) ("Arguments not raised in the briefs before the Board . . . are not permitted in the request for rehearing except as permitted by paragraphs (a)(2) and (a)(3)," neither of which applies here). *See also Cooper v. Goldfarb*, 154 F.3d 1321, 1331 (Fed. Cir. 1998) ("A party cannot wait until after the Board has rendered an adverse decision and then present new arguments in a request for reconsideration.").

Claim 55, which is representative of the claims on appeal, is directed to a "transgenic plant having incorporated into its genome a transgene that encodes a CryET33 and CryET34 crystal protein" (Decision 2). The claims of the Pershing patent¹ are directed to a "method for deploying a non-transgenic refuge crop into a field of transgenic pest resistant crops" comprising blending seeds of the transgenic and non-transgenic crops to create a uniform mixture and planting the mix in the field (Pershing, col. 34, ll. 5-14). Pershing's dependent claim 4 specifies that the transgenic pest resistant crop seeds used in the claimed method include those that produce "a binary insecticidal protein CryET33 and CryET34" (*id.* at col. 34, ll. 39-40).

We concluded that "[b]ecause the plant grown in Pershing's method is the same as the plant recited in claim 55, claim 55 is not patentably distinct from Pershing's claims" (Decision 6).

¹ Pershing et al., U.S. Patent 6,551,962, issued Apr. 22, 2005.

Appellants argue that we misapprehended the relevant case law in reaching this conclusion. Appellants argue that the “focus of a double patenting analysis is the claims – that is, are the same claims, or obvious variants thereof, being sought in two separate patents.” (Req. Reh’g 10, citing *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005), and *General Foods Corp. v. Studiengesellschaft Kohle*, 972 F.2d 1272 (Fed. Cir. 1992).)

Appellants argue that the criteria for establishing when obviousness-type double patenting should be an issue during prosecution or otherwise has been summarized in [*General Foods Corp. v. Studiengesellschaft Kohle*, 972 F.2d 1272 (Fed. Cir. 1992)] at 1278-81. . . . In *General Foods*, the Federal Circuit made clear that the focus of an obviousness-type double patenting rejection is the metes and bounds of the claims, as opposed to what has been disclosed by the claims. *Id.* (“Our precedent makes clear that the disclosure of a patent cited in support of a double patenting rejection cannot be used as though it were prior art, even where that disclosure is found in the claims.”) (Req. Reh’g 11, emphasis Appellants’.) Appellants argue that “the Board ignored the fundamental requirements and treated the Pershing patent similarly to a 35 U.S.C. §103 obviousness reference by using the disclosure of the claims, as opposed to the metes and bounds of the claims, to maintain a double patenting rejection” (*id.* at 12).

On reconsideration, we agree with Appellants that the reasoning relied on in the Decision improperly treats the method claimed in Pershing as if it were prior art in concluding that “[b]ecause the plant grown in Pershing’s method is the same as the plant recited in claim 55, claim 55 is not patentably distinct from Pershing’s claims” (Decision 6).

The issue we should have addressed is: Do the claims on appeal define something that is an obvious variant of what is claimed in Pershing? We conclude that they do not. Pershing's claims define a method of planting crops by mixing transgenic pest-resistant crop seeds with non-transgenic crop seeds and planting the mixed seeds. Each of the claims relied on by the Examiner (claims 4, 10, 25, and 31) states that the transgenic seeds express an insecticidal protein selected from:

- a recombinant acyl lipid hydrolase protein,
- a *Bacillus sphearicus* insecticidal protein,
- a *Bacillus laterosporous* insecticidal protein,
- a *Xenorhabdus* bacterial insecticidal protein,
- a *Photorhabdus* bacterial insecticidal protein,
- a *Bacillus thuringiensis* vegetative insecticidal protein, and
- one of nine specified *Bacillus thuringiensis* insecticidal δ -endotoxin proteins, one of which is the CryET33/CryET34 binary insecticidal protein expressed by the transgenic plant of the claims on appeal.

Thus, the method defined by the Pershing claims encompasses using any of a variety of transgenic seeds, only one of which will grow into the transgenic plants of the present claims; a person practicing Pershing's method would not necessarily infringe a patent claiming the instant plants. Conversely, the transgenic plants of the instant claims can be grown using methods other than the one claimed in Pershing; e.g., they can be grown without mixing transgenic and non-transgenic seeds.

We agree with Appellants that the plants defined by the instant claims are not merely an obvious variant of the method defined by Pershing's

Appeal 2007-1626
Application 10/162,464

claims, and therefore that a rejection for obviousness-type double patenting is inappropriate. The request for rehearing is granted and the Examiner's rejection is reversed.

REHEARING GRANTED

Ssc:

HOWREY LLP
C/O IP DOCKETING DEPARTMENT
2941 FAIRVIEW PARK DRIVE SUITE 200
FALLS CHURCH, VA 22042